

January 27, 2024

**VIA ECF**

Honorable Edward S. Kiel, U.S.M.J.  
United States District Court, District of New Jersey  
United States Post Office & Courthouse  
Federal Square, Courtroom 8  
Newark, New Jersey 07101

**Re: Joint Status Conference Letter**  
***U.S. ex rel. Silbersher v. Janssen Biotech Inc.***  
**Civil Action No. 19-12107(MEF-ESK)**

Dear Judge Kiel:

Counsel for the parties in the above-referenced matter respectfully submit this joint letter to advise the Court of the status of discovery in this matter in advance of the January 30, 2024, status conference.

**I. Pre-Trial Schedule**

**Relator's Statement**

Despite Relator's diligent efforts to move discovery forward, particularly over the past seven months since the current schedule was adopted (ECF No. 270), Defendants have materially delayed several critical path discovery issues, necessitating a brief extension of the current March 7, 2024, close of fact discovery.

Moreover, about a week ago, on January 19, 2024, Defendants (without ever mentioning it before) said that they would amend, for a second time, their responses to Relator's first set of interrogatories, and in connection with the anticipated amendment, produced over 600 documents, many of which relate to an Abiraterone (Zytiga) "Compound Development Team" ("CDT") through which the lead patent prosecution counsel Andrea Kamage regularly met with Defendants' key managers charged with ensuring the commercial success of Zytiga. Defendants also apparently intend, in the future, to produce additional documents concerning the CDT. These documents and information, which should have been provided to Relator over two years ago in response to Relator's March 2022 document requests, are important to core issues in this case, so much so that Defendants' counsel suggested that Ms. Kamage's deposition should not take place until after the production is completed. (Relator intends to move forward with her deposition on February 15, 2024, as explained more fully below.) Relator also expects that targeted discovery will be required in the future.

In any event, Relator wants to avoid any extension of the trial date and therefore proposes changes to extend the current fact discovery deadline by three (3) months while preserving the current pre-trial deadlines beginning with Relator's rebuttal expert reports through the pre-trial conference.

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**A. Discovery Delays and the Need to Impose Deadlines on Discovery Responses**

Relator has previously informed the Court of the many obstacles he has faced obtaining critical discovery on one of the core issues in this litigation—Defendants’ diligence during patent prosecution. Relator’s proposed solution for preventing additional future adjournments to the schedule, as well as Relator’s request for the Court to adjust the current pre-trial schedule, should be considered in the light of Defendants’ delays and Relator’s legitimate need to obtain pertinent discovery.

**1. *Delays in Identifying Who Was Involved in Patent Prosecution***

On **May 5, 2023**, Relator served interrogatories on Defendants asking them to “identify all persons” who were involved in the prosecution of the relevant Zytiga patent, including everyone who spoke to, or provided information, to the patent prosecution attorneys. Relator also asked Defendants to identify the documents they relied upon in making the Commercial Success Argument. These questions go to the heart of this case.

On **June 6, 2023**, Defendants served interrogatory responses, but instead of identifying particular individuals with whom patent counsel spoke, or specifying the documents they relied upon, Defendants simply referred to their prior interrogatory responses in the underlying patent infringement litigations (“the ANDA litigations”). Defendants also objected to specifying the documents they relied upon in making the Commercial Success Argument, because according to Defendants, that would violate the attorney-client privilege. Importantly, Defendants’ interrogatory responses in the ANDA litigations (to which they referred) represented that patent counsel ***did not speak or otherwise consult with anyone*** in Defendants’ commercial or marketing departments to verify the accuracy of the Commercial Success Argument. Naturally, Relator challenged Defendants on the sufficiency of their investigation in making such a representation, and whether it was even true.

On **July 13, 2023**, the parties submitted a joint status conference letter to the Court (ECF No. 280) raising the issues concerning Defendants’ deficient interrogatory responses and the need for Defendants to produce important ANDA litigation documents they were withholding.

Although Defendants told Relator they intended to supplement their interrogatory responses to identify additional (and previously undisclosed) individuals with whom patent counsel communicated prior to making the Commercial Success Argument, they resisted doing so for **over six months**. As of **September 8, 2023**, Defendants still had not supplemented their interrogatory answers, and the parties filed a joint status letter discussing these failures (ECF No. 286). Defendants told the Court they faced certain issues preventing them from identifying all individuals involved in the patent prosecution, and during the subsequent status conference, told Relator and the Court that they needed until **early October 2023**. The September 8 joint letter also describes Defendants’ refusal to provide critical deposition transcripts and exhibits from the ANDA litigations that Relator had been requesting for months.

Defendants failed to supplement their interrogatory responses in early October. Indeed, on **November 13, 2023**, the parties filed a joint status letter in which Defendants acknowledged

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they *still* could not identify the people with whom their patent prosecution attorneys spoke about the Commercial Success Argument. (ECF No. 293) While Defendants did eventually identify eleven (11) individuals (other than Andrea Kamage, the lead patent attorney) who were involved in patent prosecution, Defendants had failed previously to disclose the vast majority of them. This, of course, meant that Relator had to serve additional discovery directed at these newly disclosed individuals, including noticing their depositions. Defendants, however, refused to provide substantive information about their communications or diligence based on their assertion of attorney-client privilege.

The tortuous route that Relator had to navigate for over six months—just to obtain the *identity* of those involved in the patent prosecution—speaks for the need not only to extend the current fact discovery deadline, but also for the Court to impose clear deadlines for Defendants’ discovery responses to avoid any future need to delay the pre-trial schedule. We discuss in subsections 2 and 3 below Defendants’ delay tactics to avoid producing documents relating to the patent prosecution, as well as stringing along Relator with ever shifting positions on their proposal to make a limited privilege waiver.

## 2. *Delays in Producing Documents Relating to Patent Prosecution*

The joint status letters cited in the previous section (ECF Nos. 280, 286, 293) detail Defendants’ resistance to producing documents relating to patent prosecution through November 13, 2023, and Relator incorporates those here to avoid repetition.

On **November 21, 2023**, Relator served discovery requests seeking production of published and unpublished articles and memoranda from Defendants’ patent prosecution attorneys relating to patent issues relevant to this litigation. Relator also requested employee manuals, practice guides, procedures, codes of conduct, and checklists that Defendants expected their patent prosecution attorneys to follow.

Defendants gave some vague answers and blanket objections on December 21, 2023, but they refused to provide any documents at that time. Instead, Defendants told Relator they would provide a “rolling” production beginning on **January 5, 2024**. Defendants again failed to honor their commitments, and they produced *no* documents at the promised time.

Relator sent Defendants several emails and correspondence on December 20 and 21, 2023 seeking to meet and confer on outstanding discovery issues, including Defendants’ proposal of a potential limited waiver of privilege, as well as scheduling depositions and other open discovery issues. Relator also served, on **December 20, 2023**, targeted document requests requesting information from the personnel files of certain witnesses that Relator sought to depose beginning in January 2024—including the new individuals identified by Defendants in their amended interrogatory answers, which Defendants served on November 13, 2023.<sup>1</sup>

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<sup>1</sup> In their section, Defendants downplay their omissions and say that many of these individuals appeared on many documents produced by Defendants, or they were elsewhere identified for

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Having received no substantive responses to most of the issues raised, and having received no “rolling” document production, Relator sent a follow-up email, on **January 12, 2024**, again proposing a date for Ms. Kamage’s deposition (as well as dates for 27 other witnesses that Relator wanted to depose prior to March 7, 2024), and scheduling a meet and confer.

Defendants finally agreed to meet and confer on **January 15, 2024**, and on **January 18, 2024**. At these times, Defendants still had not produced any documents in response to the requests Relator served on November 21. Defendants also refused to produce documents relating to patent prosecution and seemingly rejected Relator’s proposal as to the appropriate definition of the subject matter of Defendants’ proposed privilege waiver (discussed more fully in the next section below).

On **January 19, 2024**, Defendants finally produced 611 documents, but it appears that only a small handful were responsive to Relator’s November 21 document requests and therefore part of the “rolling” production that was supposed to have begun on January 5. There were no employee manuals, practice guides, procedures, codes of conduct, or checklists that Defendants expected their patent prosecution attorneys to follow. It simply strains credulity that Johnson & Johnson and its pharmaceutical subsidiaries have *no* documents that are responsive to this category. Instead, Defendants said, for the first time, that they intended to make a *future* amendment to their answers to Relator’s interrogatories served on June 5, 2023, and that the remaining 600+ documents were being produced in anticipation of that amendment. Many of these documents apparently involve the Compound Development Team with which Ms. Kamage had regular meetings concerning Zytiga.

On **January 23, 2024**, counsel met and conferred again on Defendants’ proposal for a limited waiver of the attorney-client privilege. During that conversation, Defendants mentioned that they had recently identified and would be producing *additional* documents bearing on matters as to which Ms. Kamage was expected to testify, and that Relator should not depose her until *after* those additional documents are produced. Defendants, however, did not commit to a date certain by which they are willing to produce these additional documents, creating uncertainty over the date of Ms. Kamage’s deposition.

At Relator’s request, the parties held another meet and confer on **January 25, 2024**. During this discussion, Defendants would not specify when they intended to amend their interrogatory responses. Defendants also would not commit to a date by which they would

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other purposes. This simply misses the point. For years, beginning with the ANDA litigations, and continuing through this case until just two months ago, Defendants represented that *none* of these individuals were “involved” in patent prosecution (and therefore they could not have spoken with the patent prosecution attorneys or provided information relating to Commercial Success). While Relator readily concedes that many people at Johnson & Johnson (all the way to the top of the corporate hierarchy) *knew* that prednisone coadministration had nothing to do with Zytiga’s commercial success—the important point in discovery relating to Ms. Kamage’s diligence in prosecuting the patent is whether Ms. Kamage took the required steps to *communicate* with those who had this knowledge concerning their knowledge.

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produce documents responsive to Relator's November 21 and December 20 document requests, nor would they engage in any discussion as to their proposed privilege waiver.

3. ***Delays in Ms. Kamage's Deposition and Defendants' Limited Waiver Proposal***

With the current March 7, 2024 fact discovery deadline looming, and with numerous party and non-party depositions to be scheduled, led by the deposition of Andrea Kamage, Relator originally noticed Ms. Kamage's deposition on December 8, 2023 to commence on **January 8, 2024**. But Defendants resisted, saying that their limited waiver proposal was a gating issue that should be resolved first. Defendants insisted that the privilege issue "must be resolved before Relator's proposed deposition of Andrea Kamage." (ECF No. 302, at 6) This Court disagreed, saying that if the parties could not agree on a limited waiver proposal, then the Kamage deposition should proceed forthwith, so that the waiver questions could be decided on a "full record." (Tr. of Dec. 14, 2023 status conference, ECF No. 304, at 22) Nevertheless, the Court urged the parties to negotiate a limited waiver, saying that many of the remaining discovery disputes would "resolve" once "all those documents are turned over." (*Id.*, at 28)

Adhering to the Court's guidance, Relator wrote to Defendants' counsel on **December 20, 2023**, providing a proposed definition of the appropriate scope of Defendants' limited waiver along the lines of what the parties discussed during the December 14 status conference.

In particular, Relator proposed that the waiver extend to all issues that Relator alleges were material to patentability that should have been (but were not) disclosed to the Patent Office. Moreover, following the Court's guidance, Relator suggested that there should be no arbitrary limitation on the time period—such as the June 4, 2013 cutoff that Defendants suggested—because the subject matter definition was a sufficient limiter, and besides, Defendants made additional submissions to the Patent Office even *after* the '438 Patent issued on September 2, 2014.

On **December 22, 2023**, Relator wrote to Defendants again, requesting them to reserve dates for Ms. Kamage's deposition in mid to late January 2024, including, at the very latest, January 29, 2024, which was one of the dates offered by Defendants.

On **January 11, 2024**, Defendants responded by offering to meet and confer on January 15, 2024, but providing no substantive response or comments to Relator's limited waiver proposal or dates for Ms. Kamage's deposition. Therefore, on **January 12, 2024**, Relator sent Defendants a detailed schedule for depositions, starting with Ms. Kamage on January 25, 2022, and continuing with 27 other deponents through March 7, 2024. Relator also asked Defendants for comments on Relator's limited waiver proposal prior to the parties' meet and confer.

One hour before the parties' meet and confer on **January 15, 2024**, Defendants wrote to Relator and insisted on an arbitrary June 4, 2013 cutoff for the time period of the waiver, even though the parties had already discussed how such a cutoff was unreasonable (during the December 14, 2023 status conference). Defendants also stated that Ms. Kamage would *not* attend

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a deposition on January 25 as requested by Relator, but that she would be available beginning February 7, 2024. After Defendants refused to change their position on the limited waiver proposal during the meet and confer, Relator considered the issue at an impasse.

On **January 19, 2024**, Relator served Notices of Deposition for Ms. Kamage's deposition to commence on February 16, 2023, and for twenty (20) other depositions through March 7, 2024. Additionally, Relator inquired whether Defendants would accept subpoenas for eight (8) witnesses who either did not work directly for Defendants, or who were former employees of Defendants.

On **January 23, 2024**, the parties once again attempted to reach agreement on limited waiver. Defendants' lead counsel, Gordon Todd, and Relator's lead counsel, Nicomedes Sy Herrera, met and conferred and made some progress during this discussion. Relator was clear, however, that the framework for an acceptable limited waiver agreement would not have an arbitrary time limitation, and that the subject matter of the waiver had to embrace all the issues that Relator alleges constituted the fraud (including the misrepresentations and omissions contained in the complaint). Defendants, for their part, indicated that they intended to make an additional production of documents that were material to patent prosecution (and that Defendants were still conducting a privilege review of them), so Defendants suggested scheduling Ms. Kamage's deposition to commence *after* Defendants' forthcoming production, which would then also include any documents previously withheld as privileged if the parties could quickly agree on the limited privilege waiver.

Based on this progress, Relator's counsel re-sent his December 20, 2023 proposal describing Relator's proposed definition of the scope of the subject matter waiver, so that Defendants could provide comments on a final agreement.

Given the time constraints, Relator requested a follow-up meet and confer on January 25, 2024, to clean up some loose ends prior to the January 30 status conference. Unfortunately, Defendants' counsel were unprepared to discuss many open issues. Most importantly, Mr. Todd did not participate, and Defendants took the position that Mr. Todd was the *only* person who was authorized to negotiate this issue on behalf of Defendants (despite other counsel for Defendants having taken the lead in negotiating this issue for months). Defendants' counsel who did participate in the call declined to even discuss, much less finalize, the scope of the limited privilege waiver—all of this despite Defendants having insisted, for months, that they intended to make a limited privilege waiver of some sort, and that their forthcoming waiver was a “gating issue” that supposedly justified their delay on multiple other fronts.

During the January 25 conference, Defendants also refused to commit to a date certain when they would produce additional documents that materially relate to Ms. Kamage's deposition, including the supplemental document production that Mr. Todd referenced on January 23; and Defendants' productions of documents responsive to Relator's November 21 and December 20 requests. Defendants also refused to say when they intend to serve their amended interrogatory answers.



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On **January 26**, Mr. Todd stated that he does not believe an agreement as to the scope of a limited waiver is possible “at this point,” and that “J&J will stand on its privileges.” Given that the parties are at an impasse on this issue, and in light of the advanced stage of fact discovery, it is imperative that Relator receive clarity on Defendants’ position with respect to their potential waiver, as it would be highly prejudicial to Relator for the parties to continue with fact discovery, including depositions of key witnesses such as Ms. Kamage, with Defendants standing on their privileges, only to have Defendants change course at a later date and waive privilege.

Accordingly, Relator has requested that Defendants confirm prior to the January 30 status conference whether Defendants commit to stand on their privileges through trial, or whether Defendants instead intend to make a unilateral voluntary waiver of privilege, and the scope of that waiver.

**B. Relator’s Proposed Solutions to Avoiding Future Delays**

Based on the foregoing, Relator believes that the Court should extend fact discovery for three (3) months. Otherwise, much discovery that Relator has diligently sought would remain unattainable, severely prejudicing Relator at trial. Because Defendants’ litigation conduct has created the need for this extension, Relator believes that he should not be penalized by delaying the pre-trial conference date. Relator therefore proposes that the existing expert discovery deadlines should be adjusted so that the existing deadlines for *Daubert* and summary judgment motions are preserved. Accordingly, Relator believes that two (2) months for the parties to submit expert reports, and two (2) months to serve rebuttal reports, are ample.

Relator believes it is important for the Court to provide clarity during the January 30 status conference on the proposed adjustments to the pre-trial schedule. The sequencing and timing of depositions depend on it. Relator has already served Notices of Deposition for all party witnesses he intends to depose (including the recently identified individuals from Defendants’ amended interrogatory answers), other than 30(b)(6) witnesses. Defendants, however, have indicated that they will seek adjustments to the noticed dates (but have not identified any of them except for two). Relator is also serving approximately eight (8) subpoenas on non-party witnesses or former employees (because Defendants have stated they cannot accept notices for any of their former employees or non-party witnesses). Relator’s ability to accommodate requested changes to the deposition schedule depends on when discovery will ultimately end.

Relator also believes that the Court should impose presumptive deadlines for discovery responses. Defendants took six months to amend their interrogatory responses the first time—and the issue was a simple one, which was to make sure that they had correctly identified the individuals involved in patent prosecution. (This was also foundationally critical information, so Defendants should have known this from the very beginning: They had duties of reasonable diligence in making their initial disclosures under Fed. R. Civ. P. 26; and knowing the people with whom Ms. Kamage communicated is necessary for conducting a reasonable search for responsive documents.) Now, Defendants say they are amending their interrogatory responses

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again. To prevent delays from spinning out of control, Defendants should commit to amending their responses and producing all related documents by February 1, 2024.

Defendants have also delayed discovery by serving blanket objections and vague responses to document requests, and waiting months to actually produce documents. Fed. R. Civ. P. 34 contemplates that a requesting party may “specify a reasonable time” for the inspection of documents, and that the “production must then be completed no later than the time for inspection specified in the request,” or within “a reasonable time specified in the response.” Rule 34(b)(1)(B) and (b)(2)(B). Defendants did *not* specify a “reasonable time” in their responses, so they were therefore required to produce responsive documents by the inspection date. They have not done so. The Court therefore should order that for the remaining fact discovery, the parties must produce responsive documents by the time noticed for inspection; or if a party wishes to counter designate a “reasonable time” for production afterwards, they must specify a production date within fourteen (14) days of the noticed inspection date.

Finally, Defendants waited for many months before even raising the idea of partially waiving the attorney-client privilege, which could significantly impact the scope of fact discovery in this case, given the centrality of Defendants’ conduct during patent prosecution. If Defendants intended to partially waive the attorney-client privilege on such an important issue, they could have raised this issue *years* ago, starting with their initial disclosures. Instead, they have proceeded far down the path of fact discovery while asserting privilege, and then sought to make a significant pivot late in the game, while at the same time opposing the modest extension that Relator seeks in order to conclude the fact discovery period in an organized and efficient way.

The Court should therefore direct Defendants to either commit to stand on their privileges through trial, or make a timely, unilateral voluntary waiver of privilege. If Defendants intend to stand on privilege, then Relator intends to make a motion to preclude Defendants from introducing evidence at trial relating to the subject matter over which Defendants claim privilege. Relator also may file a motion to challenge certain privilege assertions under the crime-fraud exception—which is another reason why the Court should modify the schedule.



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C. Relator's Proposed Amendment to the Pre-Trial Schedule

The Court should amend the pre-trial schedule as follows:

Event/Deadline	Current Deadline	New Deadline
Close of fact discovery, including all fact-witness depositions	March 7, 2024	<b>June 7, 2024</b> <i>Contention interrogatories may be served based on the prior March 7, 2024 deadline under L.R. 33.1</i>
Relator's expert report(s)	May 7, 2024	Two (2) months after fact discovery, or <b>August 7, 2024</b>
Defendants' expert report(s) and rebuttal(s)	September 9, 2024	Two (2) months after Relator's reports, or <b>October 7, 2024</b>
Relator's rebuttal expert report(s)	December 9, 2024	No change (2 months after Defendants' expert reports)
Close of expert discovery	February 10, 2025	No change
<i>Daubert</i> Motions	March 10, 2025	No change
Final date for motions for summary Judgment	May 12, 2025	No change
Oppositions for motions for summary judgment	June 26, 2025	No change
Replies in support of motions for summary judgment	July 26, 2025	No change
Pre-trial conference	21 days after resolution of dispositive motions and appeals, if any	No change

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### **Defendants' Statement**

Defendants oppose Relator's request to extend fact discovery yet again. To the extent Relator asks the Court to modify any other deadlines in the Pre-Trial Schedule, Relator has made no attempt to meet-and-confer with Defendants on that schedule, his proposed changes are one-sided and unfair, and his request for a unilateral order from the Court is inappropriate and premature.

Relator has failed to diligently pursue this case for years. His alleged inability to complete discovery in the ample time that has been allotted is a problem of his own making. This Court explicitly advised Relator nearly a year ago, in March 2023, that it was imperative for Relator to begin taking depositions. *See* Dkt. 242 at 7:14-25.<sup>2</sup> Yet Relator did not issue his first deposition notice until December 2023, and waited until January 19, 2023 to issue deposition notices for other witnesses.

Now, with just over a month fact discovery remaining, Relator has advised Defendants that he plans to take 31 depositions and continues to issue inappropriate, harassing, and untimely document requests—to which he insists on receiving responses *before* depositions commence—in a transparent effort to coerce Defendants and/or the Court into relenting to yet another discovery extension.

Throughout this litigation, Defendants have responded timely and appropriately to Relator's discovery requests, consistent with their obligations under the Federal Rules. Defendants will continue to do so throughout the remainder of discovery. But Defendants vigorously oppose Relator's attempt to use his eleventh-hour burst of new deposition and discovery requests to justify extending the discovery period further. The events in dispute are already more than a decade old, and Relator filed his complaint more than five years ago. It is past time to move forward to the next phase of discovery.

#### **A. Relator Misrepresents the History of this Matter and Omits His Own Lack of Diligence.**

Relator's recitation of Defendants' purported "delays" starts in May 2023. But Relator's chronology ignores that fact discovery in this matter has been open since August 2021.

**August 2021: Fact discovery commences.** At Relator's and the antitrust plaintiffs' insistence, discovery began in August 2021 prior to Judge McNulty's resolution of dispositive motions.

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<sup>2</sup> "I do expect to see a level of diligence by the parties. . . . [T]he effort to take depositions hasn't been taken. There's been only one deficiency letter since then. And everybody's sort of sitting on the side lines. And I'm gonna make it a little bit more painful and make it a little bit more quicker than I would if I could really see that the -- that the parties have been diligent in moving things forward." *Id.*

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**September–October 2021: Defendants produce a comprehensive set of ANDA litigation materials.** By September 9, 2021—well over two years ago—Defendants had already produced 50,000 document and 4.6 million pages for Relator to review (these materials represent the entirety of Defendants’ productions from the ANDA litigation). By the end of October 2021, Defendants produced comprehensive sets of additional discovery material from the ANDA litigation, including Defendants’ interrogatory responses, requests for admission, initial disclosures, and expert reports, in addition to ANDA trial transcripts.

**May 2022: The Parties submit a joint discovery plan that calls for fact discovery to conclude on August 7, 2023.** On March 25, 2022, the Parties exchanged initial requests for production. Responses and objections followed a month later. In response to Relator’s discovery requests, Defendants agreed to meet and confer with Relator as to an appropriate time period, appropriate custodians, and a reasonable and proportional search protocol, including search terms, to identify responsive material. For other Requests, Defendants objected in full.

In May 2022, the Parties submitted a Joint Proposed Discovery Plan to the Court, which included a proposed case schedule. Pursuant to that schedule, the discovery period was set to end on August 7, 2023.

**September 2022: Defendants begin rolling productions in response to Relator’s RFPs despite Relator’s failure to substantively engage on Defendants’ objections and search protocols.** Beginning in August 2022, the Parties engaged in a series of meet-and-confers regarding the RFPs served by each party, and the corresponding responses and objections; however, beyond a dispute regarding the applicable date ranges for Defendants’ responses, Relator made no attempt to address the substance of Defendants’ Responses and Objections. Relator similarly raised no objection to the custodians Defendants chose or the search terms or protocols Defendants used. To the contrary, Relator insisted that Defendants “move forward with [their] production.” Defendants did so. On September 9, 2022, Defendants began rolling productions in response to Relator’s RFP.

**February 28, 2023: Defendants Substantially Complete Their Document Production.** Defendants’ productions proceeded apace over the next six months. In that time, Defendants produced more than 20,000 of their own documents totaling more than 115,000 pages. During this time, Defendants also produced more than 7,000 documents produced by the Institute for Cancer Research during the ANDA litigation, as well as trial exhibits from the ANDA litigation. On February 28, 2023, Defendants indicated to Relator that their productions were substantially complete. Relator raised no objections and alleged no deficiencies in Defendants’ production.

**March 14, 2023: Relator represents to the Court that he “intend[s] to schedule an initial round of depositions beginning April 1, 2023.”** In the joint status report that preceded the next status conference on March 14, 2023, Relator alleged deficiencies in Defendants’ production, claimed they justified an extension the discovery period—despite the nearly 12 months of discovery that had preceded that conference—and promised the Court that, in exchange for such an extension, Relator would “*promptly* initiate and conclude meet and confer efforts by March 28, 2023” to resolve the purported deficiencies. ECF 235 at 2. Relator informed the Court that he

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“intend[ed] to schedule an initial round of depositions beginning April 1, 2023. *Id.* Relator failed to follow through on either promise.

**May 2023: Relator serves new discovery requests rather than following through on his promise to issue deposition notices or addressing the alleged deficiencies in Defendants’ past document productions.** Nearly two months passed after the March 14, 2023 status conference without any effort by Relator to meet-and-confer on the alleged deficiencies in Defendants’ document requests and without any deposition notices. Then, on May 5, 2023 (where Relator’s story starts), Relator served *new* discovery requests—a new set of RFPs and Relator’s first set of interrogatories—without scheduling depositions or attempting to meet and confer, as promised to the Court. Based on the date Relator served these requests, only a month remained in the discovery period after Defendants’ responses were due. Defendants timely responded both to Relator’s Second RFPs and Relator’s Interrogatories on June 5, 2023. And Defendants commenced rolling productions in response to Relator’s RFPs on June 9, 2023.

*After* serving additional discovery, Relator finally asked Defendants to meet and confer on issues related to Defendants’ responses to his first RFPs. In particular, Relator sought to address objections Defendants had raised *a year* earlier—which Relator had declined to address at the time Defendants commenced their document productions in response to those RFPs, despite Defendants’ offer to engage with Relator on those issues at that time. Nonetheless, Defendants worked in good faith with Relator to resolve discrete aspects of those concerns.

**June 2023: Defendants consent to a six-month discovery extension.** To that end, in June 2023, Defendants agreed to Relator’s request to extend the pre-trial schedule by six months for the purpose of resolving pre-existing disputes and to respond to then existing requests.

**Summer 2023: Relator continues to delay scheduling depositions.** Following the extension of the discovery deadline, Relator objected to Defendants’ assertion of privilege over documents relating to the prosecution of the ’438 Patent, which was principally conducted by Andrea Kamage, an in-house attorneys at J&J. In their document productions, as reflected on the privilege log Defendants provided to Relator, Defendants withheld communications between Ms. Kamage and other company employees relating the prosecution of the ’438 Patent. These documents include, for example, communications regarding draft filings, patentability, and the compilation of information for use by the prosecuting attorneys in drafting submissions to the USPTO.

These privilege designations are appropriate. As Defendants have repeatedly stated to Relator, attorney communications and other information relating to “the preparation and prosecution of [a] patent application . . . fall within the purview of the attorney client privilege.” *In re Gabapentin Patent Litig.*, 214 F.R.D. 178, 182 (D.N.J. 2003). This privilege extends to factual communications, such as communications in which a company employee provides factual information to a patent attorney for use in the prosecution. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 805 (Fed. Cir. 2000). Because “an attorney cannot evaluate patentability or prepare a competent patent application without knowing the prior art and obtaining technical information,” that attorney client privilege precludes disclosure of communications containing such information. *Id.* at 806; *see also* *FTC v. Boehringer Ingelheim Pharms., Inc.*, 180 F. Supp. 3d 1, 30 (D.D.C.

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2016) (“For the attorney-client privilege, unlike the work-product doctrine, facts collected at counsel’s request for later use in providing legal advice are protected.”).

Despite this, Relator consistently insisted that these documents should be produced because they are “relevant” to his case. Yet the law is clear that “relevance” does not overcome privilege. As the Third Circuit has admonished, the notion that the privilege “may be waived depending on the relevance of the communication *completely undermines* the interest to be served” because “clients will face the greatest risk of disclosure for what may be the most important matters.” *Rhone-Poulenc Rorer Inc. v. Home Indem. Co.*, 32 F.3d 861, 864 (3d Cir. 1994) (emphasis added). Thus, under federal law, a client’s privileged “communications will not be disclosed”—regardless of their relevance—“unless [the client] takes the ‘affirmative step’ of waiving privilege by directly utilizing the contents of a privileged communication as part of its claim or defense.” *Sensormatic Elecs., LLC v. Genetec (USA) Inc.*, 2022 WL 14760185, at \*2 (D. Del. Dec. 30, 2022) (quoting *Rhone-Poulenc*, 32 F.3d at 864). Relator has also, at times, asserted that some “crime fraud exception” requires Defendants to produce these documents, although Relator has yet to provide any authority supporting such a theory in this case.

**Fall 2023: Defendants offer to discuss a limited privilege waiver with Relator in an effort to move the case forward.** Consistent with his lack of diligence on other matters, despite insisting that Defendants should produce privileged documents, Defendant took no affirmative steps to attempt to resolve the issue for months.

In a good-faith effort to move the case forward, on October 12, 2023, Defendants proposed that the parties consider a limited waiver of the attorney-client privilege that would allow Relator to inquire into the patent prosecution, and that would permit the production of privileged, relevant documents. To be clear, this offer was raised voluntarily by Defendants in an effort to move the case along; at no point could Relator have had any reasonable expectation that Defendants would make such an offer, or indeed, a waiver. Throughout these discussions, however, Defendants, have been clear that any waiver would extend only to the subject matter of Relator’s claims, the prosecution of the ’438 patent, and not to Defendants’ privileged materials and communications more broadly. *See* ECF 302 at 6. Moreover, Defendants suggested to the Court that by clearly defining the scope of the waiver ahead of time, the parties would be able to proceed with discovery more efficiently and significantly reduce the burden on the Court refereeing the otherwise inevitable scope disputes.

The parties have met and conferred on this potential waiver issue for many weeks, and have not reached an agreement. At the November 16 status conference, the Court encouraged the parties to continue these negotiations, but advised Relator to proceed with Ms. Kamage’s deposition with the privilege invoked if the parties failed to reach an agreement. Relator did not do so. Instead, Relator crafted new reasons to avoid taking a deposition by serving new document requests on November 21, 2023, and taking the position that the requests needed to be responded to in full before Ms. Kamage’s deposition could proceed. To the contrary, Relator’s requests served only to delay. The requests were not novel, nor did they stem from facts that Relator learned during the discovery period. They could have been issued long ago in the more than two-and-a-half-year discovery period in this case.

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**November 14, 2023: Defendants amend their interrogatory responses.** Around the same time, on November 14, 2023, Defendants provided Relator with amended interrogatory responses. Relator now contends that these amendments put him on notice—for the first time—of the identity of “vast majority” of individuals who provided information to J&J patent counsel related to the ’438 Patent application and a predecessor application, and therefore contends that the amendments necessitate an extension of the discovery period. To the contrary, Relator has been readily aware of the key individuals involved in these applications throughout the litigation.

In total, Defendants’ revised interrogatory responses named 16 individuals as being involved in the application:

- **Andrea Kamage and Timothy Tracy:** Both Ms. Kamage and Mr. Tracy are the in-house patent attorneys responsible for the prosecution of the ’438 Patent. Relator named both in his Second Amended Complaint, so cannot plausibly claim he only learned of them from Defendants’ revised interrogatory responses.
- **Denise Mattos and Laurie Tumarello (nee Phillips):** Both Ms. Mattos and Ms. Tumarello are patent paralegals who assist J&J patent attorneys in patent prosecutions. Both of their names appear on the face of documents contained in the ’438 Patent File Wrapper, a public document which Defendants identified in their initial responses to Relator’s Interrogatories on June 5, 2023. Relator did not learn of them from the revised interrogatory responses either.
- **Arie Beldegrun, Alan Auerbach, and Johann de Bono:** Again, each of these individual is named on the face of the File Wrapper, which was identified in Defendants’ initial interrogatory responses.
- **Andrew Harris, Eric Harris, Christian Nebel, Patrice Noone:** Defendants identified these individuals for their involvement in the creation of the May 23, 2013 Investor Day presentation included in the purportedly fraudulent June 4, 2013 submission to the USPTO. As Defendants’ amended responses noted, Defendants previously produced (prior to February 28, 2023) a litany of documents making their involvement in that presentation readily apparent. Moreover, both Andrew Harris and Christian Nebel were named in Defendants’ revised initial disclosures (served on March 15, 2023) as having knowledge of the Investor Day presentation. Relator has therefore been on notice of their involvement for months.
- **Paul Short:** Mr. Short served as Global Marketing Team leader for Zytiga, and Defendants previously produced (prior to February 28, 2023) multiple communications in which Mr. Short is a participant. Relator indicated that he intended to depose Mr. Short even before Defendants’ revised interrogatory responses.
- **William Daly, Arturo Molina, Michael Meyers, and Stan Panasewicz.** Each of these individuals appears prominently on numerous – likely thousands – of documents produced to Relator in 2021 and 2023. These documents include substantive correspondence, memoranda, and other records. Simple review of the produced



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documents would have identified these individuals' involvement in the various issues Relator seeks to raise as well as their relationships with patent counsel.

Thus, at the very most, Defendants provided four new names for Relator's consideration in the November 14, 2023 amended interrogatory responses: William Daly, Arturo Molina, Michael Meyers, and Stan Panasewicz. And Relator should readily have been able to identify them as relevant a long, long time ago. This is a far cry from the "vast majority" that Relator insists were missing.

Relator wrongly claims that Defendants previously "represented that *none* of these other individuals were 'involved' in the patent prosecution." To the contrary, in their initial interrogatory response, Defendants simply identified information responsive to Relator's request and reserved their right to supplement the responses based on further investigation. Defendants' amended responses did precisely that. Moreover, the question of who J&J in-house patent counsel consulted during the patent prosecution is a classic example of the type of question the Court previously admonished Relator to ask in a deposition rather than continuing to insist on "litigat[ing] the case through the interrogatories and document production" well past the date on which Relator represented that depositions would commence. ECF 311 at 29:12-21.

**December 2023: Relator serves additional discovery requests rather than proceeding with depositions.** On December 14, 2023, the Parties appeared before the Court again for a status conference.

Defendants requested that the Court consider a motion for a protective order defining the scope of the privilege waiver before depositions commenced. This Court declined to do so and stated that, if the parties did not reach an agreement on waiver, the Court preferred to consider any privilege disputes after Defendants invoked the privilege during depositions, and the Court had the benefit of considering the privilege issue with the benefit of a full deposition transcript. Defendants have accepted that guidance and do not intend to request a protective order prior to depositions.

Once more, this Court admonished Relator to take a deposition if the Parties did not reach an agreement on a limited waiver. *See* ECF 304 at 24:5-9 ("But without an agreement we can't just . . . stop litigation and say stop depositions from going forward. . . . Let's do it now."). Yet, rather than notice a deposition, Relator *again* served new discovery requests that he insisted required a full response before depositions could commence. As with the RFPs Relator served in November 2023, the manifest intent of these requests was to delay depositions and increase the pressure on Defendants and the Court to allow yet another extension. Moreover, Relator's requests were blatantly overbroad as they sought personal information for more than two dozen individuals, including highly confidential tax information.

**January 12, 2024: Relator seeks to schedule at least 30 depositions.** On January 12— with less than two months of discovery remaining—Relator provided Defendants with a highly

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ambitious proposed deposition schedule: 31 witness within approximately one month.<sup>3</sup> Prior to this date, Relator had not previously indicated to Defendants that he had any intention of deposing a majority of the individuals on this list.

**January 15 & 18, 2024: The parties reach an impasse on the privilege waiver.** On January 15, the parties met and conferred on multiple topics, including the privilege waiver. At the conclusion of that discussion, Defendants indicated that the Parties had reached an impasse. Defendants advised Relator that they would not waive privilege and were prepared to proceed to depositions without an agreement in place. On January 18, the parties met and conferred again and Defendants reiterated these points.

**January 19: Relator issues 20 new RFPs.** The next day, on January 19, Relator formally served J&J with 20 deposition notices. Additionally, Relator served 20 new RFPs. Despite his insistence that the new requests are “narrow,” they demand that Defendants run new search terms across 20 different custodians. Relator again insists that these requests are critical and must be produced prior to any deposition. But again, Relator’s failure to serve these request until now seemingly contradicts those assertions. The requests are untimely, unreasonable, and motivated to delay.

**January 23-26: The parties reengage on the privilege waiver, but do not reach an agreement. Defendants reiterate their prior statements that they are not waiving privilege and are prepared to proceed to depositions without a waiver agreement.** Counsel for the parties discussed the limited privilege waiver once more on an informal basis, on January 23. No agreement was reached, and on January 26, Defendants informed Relator in no uncertain terms that they would not be waiving the attorney-client privilege.

## **B. Relator’s Proposed Motion *in Limine* is Premature.**

Relator states that, if Defendants do not waive privilege now, he will imminently file a motion “to preclude Defendants from introducing evidence at trial relating to the subject matter over which Defendants claim privilege.” Any such motion would be untimely. The appropriate time for a motion *in limine* is after the Court has established its pre-trial order, not while fact discovery is still ongoing. Indeed, Relator has yet to detail in response to Defendants’ discovery requests the full and final universe of statements he claims were false, the claims for payment to which they relate, and the particular drug programs he claims were defrauded. Nor has Relator yet supplied his expert reports, where apparently his actual case will appear. Relator’s suggestion that Defendants should be locked into the scope and manner of their defense before his affirmative case is revealed is, frankly, absurd. In any event, Relator has identified no authority—and Defendants are aware of none—that compels Defendants to make an irrevocable decision about

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<sup>3</sup> Pursuant to the scheduling order, Relator is permitted 120 hours of deposition time, a significant increase over what Relator would have been allowed under the Federal Rules. This provision, however, was premised on Relator’s then-stated desire to depose each of the 13 generic manufacturers who filed ANDA applications. Nonetheless, even with his increased time limits, it is clear that Relator’s deposition proposal is woefully inefficient and serves only to harass and burden J&J employees with minimal connection or knowledge of the facts of this case.

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their privilege before Relator has presented a single piece of tangible evidence (rather than the allegations in his complaint) to support his claim. Relator, not Defendants, bears the burden of proof in this case, and Defendants are entitled to complete fact and expert discovery on Relator's claims before making any final decisions regarding any defenses or privileges they may raise at trial. Moreover, Relator has made no particularized objections to any specific document or deposition testimony withheld on account of privilege. All of those issues should be resolved before any such motion *in limine* is considered.

**C. Relator's Extension Request is Unwarranted and Procedurally Improper.**

Given Relator's failure to prosecute his case, Defendants oppose any extension to the discovery schedule. As illustrated above, the delays in this case are principally of Relator's own making. To the extent Relator believes it is not possible for him to complete the 31 depositions he seeks or litigate Defendants' objections to his late-breaking RFPs in the remaining time allotted for fact discovery, these are issues Relator should have pursued at least a year ago, rather than now. The Court should deny any request for an extension on that basis alone.

As noted above, to the extent Relator seeks to extend any deadline besides the close of fact discovery, his request is procedurally improper because he has made no effort to meet and confer with Defendants on those dates. Relator's proposal is also improper because it seeks to shorten *only* Defendants expert report deadline from the preexisting schedule. That would be manifestly unfair as a general matter. It would be grossly unfair in this case, where Defendants are apparently going to learn the bulk of Relator's allegations through his expert reports, as he has been unable to, or has refused to, articulate them in fact discovery. This Court should refuse the request.

**D. Defendants are working to accommodate Relator's deposition requests and will timely notice any objections.**

Defendants will make witnesses available for deposition prior to the close of fact discovery, and will timely note any objections to Relator's deposition notices.

The parties have agreed that the deposition of Andrea Kamage, the J&J in-house patent counsel principally responsible for the prosecution of the '438 application will take place on February 15, 2024.

Defendants have also furnished Relator with a proposed date for the deposition of Timothy Tracy, the J&J in-house patent counsel who took over that responsibility from Ms. Kamage in 2013. Defendants have also informed Relator that the two paralegals who assisted Ms. Kamage and Mr. Tracy are available for deposition on their notice dates.

These four individuals are the only witnesses actually involved in the prosecution of the '438 patent, including all of the submissions made to the Patent Office, which is the gravamen of the fraud Relator alleges.

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## II. Party Discovery

### **Relator's Statement: Relator's Discovery Requests and Defendants' Responses**

Other than what Relator has described in Section I(A)-(C), *supra*, there are a few additional issues as to which Relator intends to submit a discovery letter unless the parties can agree to a resolution:

1. Defendants have objected to producing certain “unpublished” articles or memoranda drafted by the relevant patent prosecution attorneys (Andrea Kamage and Timothy Tracy) relating to commercial success, the False Claims Act, inequitable conduct, and other intellectual property issues relevant to this case. (Request for Production Nos. 61-63.) Much of the parties’ dispute may be resolved with a final agreement on Defendants’ limited privilege waiver. Nevertheless, Defendants appear to object to general articles or memoranda drafted by the patent attorneys, but which remain unpublished. If so, Relator may have to move for their production.

2. Defendants have objected to producing certain documents from the personnel files of employees that Relator wishes to depose. These include redacted tax forms that indicate the EIN number and identity of the specific employer entity. Unless the parties can reach agreement on the production of sufficient documents that would allow Relator to identify each corporate entity that paid each witness—and for Ms. Kamage and Mr. Tracy, whether their compensation was tied to successfully obtaining patents—Relator may have to move to compel.

3. Defendants have failed to produce any memoranda, checklists, codes of conduct, or other operating procedures or manuals governing patent prosecution for Johnson & Johnson’s patent department. (Request for Production No. 62.) If Defendants persist, Relator may have to move to compel.

4. Defendants have failed to produce requested information from the personnel files of witnesses noticed for deposition. (Request for Production Nos. 65-67.) If Defendants persist, Relator may have to move to compel.

5. Relator intends to file a discovery letter seeking to remove the “Outside Counsels’ Eyes Only” (OCEO) designation for documents produced by Defendants (as opposed to generic manufacturers). The basis for doing so is that the OCEO designations preserved in the Confidentiality Order were intended to facilitate the production of third party generic documents—and not to prevent Relator from reviewing documents produced by *Defendants*.

**Defendants' Statement: Relator's RFP's are late and largely improper. Defendants will respond promptly to any discovery letter Relator wishes to submit, but they are not grounds for an extension.**

### **Relator's Items #1 - #4.**

Despite representing to this Court in February 2023 that he was prepared to take depositions, including the deposition of Ms. Kamage, in April 2023, Relator has issued three new

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requests for the production of documents that he now claims are essential to conducting those depositions. (The requests were issued on November 21, 2023; December 20, 2023; and January 19, 2023.)

These requests are egregiously late, consistent with Relator's persistent lack of diligence in prosecuting his case. They appear designed to lure Defendants and/or the Court into consenting to an unnecessary extension of the fact discovery deadline. Defendants have already produced 6.2 million pages of documents to Relator in this litigation, including documents from the custodial files of Ms. Kamage. Relator's new document requests could have been issued years ago. Relator does not and cannot reasonably claim that any of these requests were precipitated by newly-discovered evidence.

Many of these requests are also inappropriate. For example, Relator seeks documents that indisputably are privileged, such as legal memoranda on patent prosecution issues. In addition, Relator seeks J&J tax records for dozens of current and former employees, which the Third Circuit has held are presumptively confidential and their disclosure is disfavored as a matter of public policy. *See DeMasi v. Weiss*, 669 F.2d 114, 119–120 (3d Cir. 1982) (“[I]ndividuals have legitimate expectations of privacy regarding the precise amount of their incomes,” and Congress has established that this information “need be divulged only to the taxing authorities, and to them with an expectation of confidentiality.”) (citing I.R.C. § 6103).

Defendants have furnished Relator with written responses to these requests on the dates contemplated by the Federal Rules. Defendants have also produced documents in response to Relator's Third Request for Production (published opinions and articles authored or co-authored by Andrea Kamage and Timothy Tracy), and have met on conferred with Relator on multiple occasions on the other requests, including on December 7, 2023; January 15, January 18, and January 25, 2024.

Relator has stated that he remains unsatisfied with Defendants' responses and plans to submit discovery letters to the Court addressing these requests, but has so far failed to do so. Defendants have informed Relator that they will respond promptly to any such discovery letter.

In the meantime, however, any dispute regarding these late-issued requests do not justify any extension of the fact discovery deadline. Defendants have responded to these requests timely and appropriately. To the extent Relator wishes to submit discovery letters on them, Defendants will do the same.

**Relator's Item #5.** During the ANDA Litigation, certain documents were produced by both Defendants and generic manufacturers for “Outside Counsel's Eyes Only” review. The Discovery Confidentiality Order (“DCO”) entered by this Court kept those designations in place without restriction. *See* ECF 162 at 4. Relator further agreed that he would be excluded from the definition of “counsel,” such that he was not permitted to view OCEO documents.

Relator now seeks to undo that agreement at this late stage of the litigation, and plans to ask this Court for an order expanding this provision to allow Relator personally to review all such documents. This is procedurally improper. As Defendants have informed Relator, the DCO

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contains a mechanism for Relator to challenge OCEO designations from the prior litigation, to the extent the document was *wrongly* identified as OCEO in the *prior litigation*. *Id.* at 7. But to do so, Relator must first “particularly identify the Protected Information” that he “contends is not properly designated as Protected Information, along with the reasons supporting that contention.” *Id.* Relator has thus far refused to do so. Accordingly, Defendants have informed Relator on multiple occasions that they oppose this request, and will timely reply to any discovery letter he submits. Relator’s failure to submit a discovery letter on this topic yet is not a basis to extend the fact discovery deadline.

### **Defendant’s Statement**

#### **B. Defendants’ Discovery Requests and Relator’s Responses**

### **Defendant’s Statement**

#### **1. Relator Refuses to Provide Defendants with Topics for His Proposed 30(b)(6) Depositions.**

On January 12, Relator informed Defendants that he intends to depose as many as 31 witnesses before the close of fact discovery on March 7.<sup>4</sup> On January 19, Relator served Defendants with deposition notices for 20 individuals, and Relator has proposed dates for 11 more, including dates for two 30(b)(6) depositions. Although Relator provided Defendants with a partial list of 30(b)(6) deposition topics, he has refused to provide a complete set of topics or to commit to a date certain by which he will do so. Yet, at the same time, Relator has demanded that Defendants provide availability for dozens of witnesses Relator intends to depose in their individual capacities. This is inefficient and unnecessarily burdensome to Defendants. Defendants anticipate—and Relator has acknowledged—that many of the witnesses for whom Relator has noticed or proposed depositions may appropriately be designees for certain 30(b)(6) topics, including Andrea Kamage, who Relator insists on deposing first. Defendants therefore has asked Relator to provide a complete list of 30(b)(6) topics before the start of any depositions, so Defendants can determine whether any individuals Relator seeks to depose in their individual capacities will also be designated as a 30(b)(6) witness for certain topics. This approach would sensibly avoid the unnecessarily recalling of witnesses for multiple depositions. By refusing to provide Defendants with a complete list of 30(b)(6) topics, Relator appears to be seeking precisely that result. This is gamesmanship designed to increase the expense and inconvenience of his already burdensome requests.

Relator responds that the partial list of topics he has provided includes all the topics for which *Relator thinks* the first individual deponent, Ms. Kamage, should serve as a 30(b)(6) witness. But Relator ignores that under the plain text of the Rule it is *Defendants’* prerogative to

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<sup>4</sup> The Scheduling Order permits up to 120 hours of depositions; a significant increase over what Relator would have been allowed under the Rules in order to accommodate his then-representation that he would have to depose each of the 13 generic drug manufacturers who entered or considered entering the abiraterone market.)



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designate the appropriate witness for each 30(b)(6) topic, not Relator. *See* Fed. R. Civ. P. 30(b)(6) “the *named organization* [in a 30(b)(6) deposition notice or subpoena] must designate . . . persons who consent to testify on its behalf,” not the Relator (emphasis added)).

Defendants thus ask this Court to instruct Relator to provide a complete list of 30(b)(6) topics by no later than February 8, 2024, one week before the first scheduled deposition.

**2. Relator has Improperly Redacted Non-Privileged, Substantive Information from Produced Documents.**

As previously discussed with the Court, Defendants have awaited Relator’s production of non-privileged memoranda provided to his consulting clients that relate to the patent topics at issue in this case for more than six months. Since the last status conference, Relator produced only ten documents in response to this request. Relator purports that this set of documents encompasses the entire universe of advice that Relator offered through his consulting business over more than seven years on intellectual property issues implicated by this case. That strains credulity. Defendants reasonably believe that Relator is withholding documents responsive to this request. Relator’s production contains analyses that focus on particular stages of a patent litigation, including analyses following trial, a *Markman* hearing report, and a pre-trial “cheat sheet.” This would tend to suggest that Relator would prepare *multiple* analyses across the lifecycle of any particular litigation. Yet, Relator’s production contains only one-off analyses for each litigation implicated by his production. For example, although Relator produced a “bench trial cheat sheet” analyzing Hatch-Waxman litigation concerning a branded drug, Treanda, no corresponding *Markman* hearing report exists. Defendants intend to submit a discovery letter to the Court on this topic, seeking to compel the production of the withheld documents.

Separately, Relator has improperly redacted one of these documents. Defendants have consented only to redactions of these documents that are necessary to protect the identity of Relator’s clients. Relator’s redactions go far beyond his client identities, however, and Relator has not articulated a valid justification for them. As an initial matter, Relator cannot claim privilege over these documents because they contain communications he undertook in his capacity as a patent consultant, not on an attorney-client basis. Relator’s redactions also are not plausibly necessary to protect Relator’s clients’ identities. Instead, Relator redacts entire pages of correspondence from the documents. It is apparent from the face of this document that the redactions conceal facts that inform Relator’s analysis. For example, in one such document, Relator says “I agree with Gaston” [i.e., Relator’s colleague] that the case they are discussing “is very close.” Yet, Gaston’s preceding message to Relator is redacted. This is plainly improper, particularly given that Relator adopts this analysis as his own. Defendants thus plan to submit a discovery letter asking this Court to order Relator to provide updated versions of these documents with only client identifying information (i.e., names, email addresses, addresses, and phone numbers) redacted and to preclude Relator from redacting documents in the future other than to protect privileged information or client identifying information.

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**3. Defendants Request Permission to Submit an Additional Discovery Dispute Letter Regarding Relator's Deficient Interrogatory Responses.**

Defendants also foresee the need to submit a further discovery letter to resolve deficiencies in Relator's amended interrogatory responses, despite Defendants' multiple prior attempts to meet and confer with Relator on these issues. Specifically, the following responses remain deficient:

Interrogatory 1. This Request asks Relator to identify each instance in which he was in contact with the federal or any state governments in connection with the subject matter of this litigation. This information is fundamental to Relator's claim. As a *statutory pre-requisite* to filing an action under the False Claims Act, and many state analogues, Relator must demonstrate that he has furnished the government with a copy of the complaint and a written disclosure of all material evidence and information Relator possessed. 31 U.S.C. § 3730(b)(2); *see also, e.g.*, Fla. Stat Ann. § 68.083(3); N.J. Stat. § 2A:32C-5.d; Tex. Hum Res. Cod Ann. § 36.102(a). Defendants thus issued this interrogatory to determine whether Relator satisfied these requirements. Defendants are entitled to a complete response.<sup>5</sup>

Defendants have clearly communicated the deficiency in Relator's response on several occasions. This Request calls for: (1) the date of each communication; (2) the participants in each communication; and (3) the manner of each communication (i.e., email, telephone, or an in-person meeting). At best, Relator provides only the date of some communications, and has offered no basis for his refusal to provide the additional information (such as the participants or manner of communication) called for by the request.

Interrogatories 17 & 18. These requests seek information on the processes and mechanisms through which Relator allegedly false claims were submitted to and processed by each federal and state government program at issue. As an element of his claim, Relator must demonstrate that Defendants actually submitted or caused the submission of false claims for payment to demonstrate causation under the FCA. *See* 31 U.S.C. § 3729(a)(1). "[E]vidence of how the claim makes its way to the government" is directly relevant to this inquiry. *United States ex rel. Petratos v. Genetech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017). Relator also must prove that the Defendants' allegedly false statements were material to the government's decision to make a payment on the particular claims at issue. *Id.* at 489. Again, the process through which each government agency receives, reviews, processes, and ultimately pays a particular claim is a critical part of a Court's materiality analysis. Relator's current responses fail to identify these aspects of his claim.

Interrogatory 11. Relator's amended response to this Interrogatory 11 is inadequate for the same reason. This request asks Relator to describe with particularity the false claims he alleges were submitted to the federal or state governments. Relator's answer falls short of his obligations

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<sup>5</sup> Relator's reasoning for his failure to respond is puzzling. He has explicitly represented to the Court that he intends to present fact testimony about his investigation, including "the provision of the draft complaint to the federal and state governments prior to filing this lawsuit." ECF 280 at 6. But Relator has represented to Defendants that "[t]here are no communications" of this sort, indicating that Relator lacks foundation to offer that proposed testimony.

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for two reasons. First, it fails to identify the specific condition for payment in each program that Defendants purportedly failed to comply with. Second, Relator has put a myriad of state and federal programs at issue in his Second Amended Complaint, yet fails to identify which particular programs and which particular aspects of those programs that Defendants purportedly ran afoul of.

These requests are critical to understanding the metes and bounds of Relator's claims and cannot be obtained through other discovery mechanisms. Defendants are mindful of the Court's prior guidance that contention interrogatories should be reserved for the final two months of discovery. However, because fewer than 60 days of the discovery period remain, Defendants submit that it is necessary for Relator to provide complete responses to each of these interrogatories now. As such, Defendants request this Court's permission to submit a further discovery dispute letter to resolve these issues.

### **Relator's Statement**

None of the discovery issues that Defendants raise are ripe for this Court's consideration, because there have been no meaningful meet and confers concerning them. Defendants served their deficiency letter raising these issues on January 25, 2024. Relator offered to meet and confer with Defendants within 5 days, and Defendants have yet to schedule that date.

Given the more weighty and pressing issues before the Court, the Court should simply disregard Defendants' points until the relevant issues have been fully ventilated between the parties. Nevertheless, Relator offers the following summary for the sake of efficiency and possibly avoiding future disputes.

1. **30(b)(6) topics.** The fact that Defendants have raised this issue is ironic, because when Relator first noticed Ms. Kamage's deposition, Relator provided Defendants with a list of 30(b)(6) deposition topics related to patent prosecution with the hope that Ms. Kamage could testify both individually and as a corporate representative on these topics. When Defendants' counsel rejected this suggestion and insisted that Relator provide a full list of all 30(b)(6) topics regardless of their relevance to Ms. Kamage, Relator's counsel wrote:

What we proposed is intended to simplify matters: If Ms. Kamage will be testifying as a corporate representative on the patent prosecution topics, it might make sense to have her testify in both capacities at the same deposition. We can leave the other topics for when we depose individual witnesses who may likely be designated representatives for those other topics.

Defendants rejected this common-sense suggestion. Accordingly, Relator intends to serve 30(b)(6) deposition notices as provided under the Federal Rules of Civil Procedure. He does not need to justify his choice in doing so to Defendants, although counsel notes that a sound litigation strategy is to save 30(b)(6) depositions so that they can be targeted to issues that need to be clarified or emphasized based on 30(b)(1) testimony. Defendants simply provide no authority that requires Relator to do otherwise.

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## 2. **Relator Has Not Improperly Redacted Non-Privileged, Substantive Information**

Defendants assert that Relator's production of non-privileged memoranda provided to his consulting (and not legal) clients is deficient. That is not true. To address Defendants' unfounded assertions: Relator never claimed that the produced documents "encompass the entire universe of advice . . . over more than seven years on intellectual property issues implicated by this case," as claimed by Defendants. The applicable document request is directed to narrow issues—inequitable conduct, commercial success, and the effect of patent thickets. Those issues do not arise within many patent pharmaceutical cases that Relator has handled in a non-legal consulting role. Defendants also complain that the produced reports only pertain to specific stages of a given litigation, rather than the entire life-cycle. That speaks to the needs of Relator's consulting (as opposed to legal) clients, who often invest around a specific tradeable litigation event. In other words, had Defendants taken the time to meaningfully confer with Relator, they would know that their accusations are baseless.

Defendants focus on an email that included redactions removing the client's identity, but also the client's proprietary information related to the client's trading strategy that is not relevant to this matter. Relator is prepared to produce this email *in camera*. In short, Defendants' grievance is not ripe for the court's attention, and it makes much-ado-of-nothing on an issue that is marginal at best to this case. At the end of the day, Defendants' liability will turn on applicable patent laws, not upon Relator's prior private opinions about unrelated litigations. ¶

## 3. **Relator's Interrogatory Answers are Sufficient**

None of Defendants' complaints about certain interrogatory responses are ripe, nor are they meritorious.

First, Defendants ask Relator to identify communications between him and government officials. There are no such communications, because Relator never communicated directly with the government, but only through counsel. And with respect to counsel's communications to the government, particularly the U.S. Attorneys' Office, the parties had previously agreed that they would produce a privilege log only with respect to *pre-filing* communications, because logging post-filing communications that only involved counsel is generally avoided because it's a monumental waste of time for both parties since those communications are privileged, protected by the work product doctrine, or both.

With respect to the remaining interrogatories, Relator believes that his answers are more than adequate and would be willing to meet and confer with Defendants, or brief the issue with the Court, if necessary.

## III. **Government Discovery**

### ***Relator's Position***

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Relator served the subpoena signed by the Court directed to the United States Department of Veterans' Affairs (the "VA"). The government has accepted the subpoena, and Relator expects to receive the VA's data in early February 2024.

During the December 14, 2023, status conference, the parties discussed the Court's issuance of a subpoena to the Centers for Medicare and Medicaid Services ("CMS"). Defendants objected to the entry of a separate confidentiality order for CMS in addition to the existing one at ECF No. 175.

Relator informed Defendants that CMS was willing to use the existing confidentiality order, and that Defendants' remaining objections were therefore satisfied. On January 19, 2023, Defendants informed Relator that they had no further objection to the proposed subpoena and proposed order. Accordingly, Relator files contemporaneously with this status letter the proposed subpoena to CMS along with a proposed order. Because of Defendants' delay in agreeing to the CMS subpoena, Relator may not receive CMS's data until after the current March 7, 2024 discovery deadline—which is another reason for the Court to extend the pre-trial schedule as requested.

### ***Defendants' Position***

#### **CMS**

Relator's desire to subpoena CMS is not grounds for an extension. It is Relator's prerogative to pursue his own discovery. Relator does not need Defendants' consent to issue a subpoena to CMS, and failure to issue a subpoena to CMS earlier in this litigation is again a problem of his own making.

As indicated at the prior status conference, Defendants were willing to meet and confer with Relator and CMS on the scope of the protective order, but did not consent to Relator's insistence on the unilateral entry of a new protective order. More fundamentally, any concerns about the protective order are entirely independent from whether or not Relator issues a subpoena to CMS. Relator is free to pursue third party subpoenas absent Defendants' consent. Defendants would have expected a reasonably diligent litigant to seek the information he now demands from CMS at the outset of this litigation. But, as with his other discovery, Relator left it for the last minute. That is not a basis for extending discovery.

#### **United States Patent & Trademark Office**

As indicated in prior joint status reports submitted to the Court, *see e.g.*, ECF 293 at 13, Defendants served a subpoena duces tecum on the United States Patent and Trademark Office ("USPTO") in connection with this action. Defendants' negotiations with USPTO regarding that request have reached an impasse. On January 23, 2024, Defendants filed an action to enforce the subpoena in the United States District Court for the District of Columbia. *See Janssen Biotech, Inc. v. U.S. Patent & Trademark Office*, 24-mc-00006-JDB (D.D.C. Jan. 23, 2024). USPTO's response to Defendants' motion to compel is due on February 6, 2024. Defendants will continue to keep the Court apprised of further updates in that action.

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#### IV. Other Issues

The parties agree that no issues other than those described above need be addressed at this time.

Respectfully yours,

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